No. 13241.

IN THE

United States Court of Appeals

FOR THE NINTH CIRCUIT

RUTH B. DROWN, an individual trading as DROWN LABORATORIES,

Appellant,

vs.

UNITED STATES OF AMERICA,

Appellee.

APPELLEE'S BRIEF.

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MISCELLANEOUS

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APPELLEE'S BRIEF.

I.
Statement of Jurisdiction.

Pursuant to 21 U. S. C. 331(a), 21 U. S. C. 333(a), and 18 U. S. C. 3231, the District Court had jurisdiction to try the defendant-appellant.

Under 28 U. S. C. 1291, this Court has authority to review the judgment of the District Court.

II.
Statement of Facts.

A. Summation of Case.

The one-count Information filed in this case charges the defendant Ruth B. Drown with violating the Federal Food, Drug, and Cosmetic Act by causing a misbranded device called "Drown Radio Therapeutic Instrument" to be

delivered for introduction into interstate commerce. [R., Vol. 7, p. 2.] The Information charges that the device was misbranded by reason of claims in its labeling that were allegedly false and misleading both with respect to *this* device and with respect to *another* device which is also marketed by the defendant.

At the outset of this proceeding in the District Court, defendant filed a Motion to Dismiss asserting she had not caused the delivery of said device for introduction into interstate commerce, as charged. [R., Vol. 7, p. 11.] This Motion was submitted upon a written Stipulation as to Facts [R., Vol. 7, p. 46], and was denied by the lower court in a memorandum opinion. [R., Vol. 7, p. 13.]

After a two-week jury trial, the defendant was found guilty as charged [R., Vol. 7, p. 23], and was sentenced on October 22, 1951, to pay a fine of $1000. [R., Vol. 7, p. 36.] On October 25, 1951, defendant filed a Notice of Appeal. [R., Vol. 7, p. 37.]

B. Nature of Defendant's Devices.

The defendant, Dr. Drown, is a chiropractor who does business in Hollywood, California, under the fictitious name of Drown Laboratories. [R., Vol. 7, p. 46.] She manufactures, sells and uses in her practice, a number of devices [including the two in question, Exs. 9 and 11] for which she claims remarkable therapeutic and diagnostic properties in her labeling.

For example, the Drown Radio Therapeutic Instrument [Ex. 9] is represented as capable of eliminating a lump in the breast and preventing cancer therefrom; as efficacious in treating kidney and bladder complications, tipped uterus, streptococcus in the ureter and urethra, cirrhosis, carcinoma of the right kidney, fibrous adhesions in the brain, heart

trouble of many years' standing, explosions in right ear when falling asleep, constipation, headaches, abscesses, loss of speech and memory, worry, fear and nervousness, affections of the kidney, gall bladder, colon, liver, ovary, small intestine, bile, uterus and rectum; and for the efficacious treatment of many other conditions specified in the Information [R., Vol. 7, pp. 3-5], surpassing any other known method of therapy. [Ex. 2 (see case histories); Ex. 5.]

Another Drown Radio Therapeutic Instrument [Ex. 11] is cased in a larger box and is represented as having not only all of the *therapeutic* qualities attributed to the smaller box [Ex. 9] but also extraordinary *diagnostic* capacities such as the ability to measure the functions of the body and its various parts, count blood cells, analyze urine, ascertain blood pressure and body temperature, uncover many obscure conditions, etc., simply by "tuning" into the body. [Exs. 2, 10.]

These devices use no commercial electricity; they are represented as employing the patient's own body energy in diagnosis, remedy selection, and treatment. [Ex. 2.] "By body energy we mean that electro-magnetic force which is generated by the combination of the minerals and the fluids in the body, as well as the total life force, which is an invisible light ray just past the white light in the spectrum, as the infra-red is beneath the spectrum." [Ex. 2.]

Defendant's theory of vibration is basic to her espousal of these devices. ". . . under the laws of vibration, each individual has a rate of vibration peculiar to himself. In addition, each organ, gland, etc., in the body has its own rate of vibration. Likewise various diseases all vibrate

to specific rates (slower or coarser than the normal body rates and more akin to earth vibrations)." [Ex. 2.]

In treating a patient, defendant asserts—so far as we are able to comprehend what she says—that the device captures the body energy emanating from the patient and sends that energy back to the diseased area of the patient's body at the vibration rate previously found in diagnosis as being appropriate for the treatment of that particular area. This focuses the body energy on that area and steps up the vibrations there. As a result, the diseased cells "automatically fall away since disease cannot live in the higher rate of vibration." [Ex. 2.]

Both diagnosis and treatment, the defendant claims, may be accomplished either directly or by "remote control." When the patient is physically close to the instrument, two pieces of metal attached to wires plugged into the instrument are placed upon the body, one on the feet and the other on the stomach. A drop of the patient's blood on blotting paper is placed in a slot in the device, and an unopened ampul said to contain one of several chemicals may be placed in a well on the face of the device. [R., Vol. 1, pp. 24-25.]

When the patient is not physically close to the device, the two pieces of metal are clamped together with a drop of the patient's blood on blotting paper between them. The patient can be anywhere, even thousands of miles away, yet allegedly be completely diagnosed and receive treatment. It is wholly immaterial that the patient's sex, symptoms, and medical history are unknown to the operator of the device. [R., Vol. 1, pp. 25-26, 21; Vol. 2, pp. 435-439.]

The Government's witnesses included some of the country's outstanding men of science with specialized training

and experience in the fields of physics, electrical engineering, radiology, physiology and pharmacology, urology, cancer, thoracic surgery, and physical medicine.

Two qualified witnesses had taken the instruments apart, studied their circuits, and testified as to their physical properties. Dr. Moses Greenfield is a physicist who did research for the Navy during the war, represented the Navy at the Bikini atom bomb experiment, did research in physics with North American Aviation since the war, is associated with the School of Medicine at U. C. L. A. in the field of atomic energy, and is a consultant to the Atomic Energy Commission. [R., Vol. 1, pp. 184-186 and 211.] He testified that Exhibit 9 and Exhibit 11 are identical in function. [R., Vol. 1, p. 196.] Essentially, each device consists of a wire with two dissimilar metals as electrodes at either end. When the circuit is completed by placing the electrodes in contact with the human body or with any other conductor of electricity, a minute flow of electrical current is generated between the two metals, and this flow is measured by the microammeter in the device. [R., Vol. 1, pp. 187-190.] This is in effect the way a chemical battery operates. If two dissimilar metals are used in any circuit, there will be a flow of current between them measurable on a microammeter. [R., Vol. 1, pp. 197 and 199.] Defendant's devices are incapable of detecting, measuring, or transmitting electro-magnetic radiation of any kind. [R., Vol. 1, pp. 234-235.]

Mr. Robert J. Stratton is a radio engineer for the Federal Communications Commission with extensive experience in electrical engineering with the Commission and the Columbia Broadcasting System. [R., Vol. 1, pp. 86-87.] He took apart the two devices [Exs. 9 and 11] and made a diagram of each of the circuits which diagrams

are in evidence as Exhibits 12 and 13. His description of the operation of these devices is substantially the same as that of Dr. Greenfield. [R., Vol. 1, pp. 90-94.] These devices are incapable of measuring or transmitting radio waves. [R., Vol. 2, pp. 243-244.] There is nothing in the boxes of either Exhibit 9 or Exhibit 11 except the circuit. [R., Vol. 2, pp. 245-246, 248.]

Mr. Stratton had occasion to investigate Dr. Drown's activities in 1947 on behalf of the Federal Communications Commission to ascertain whether radio waves were emanating from any of her devices, and he determined that none of her equipment could possibly radiate, including devices of the same construction as Exhibits 9 and 11. [R., Vol. 2, pp. 249-253, 257-258.] Dr. Drown at that time advised Mr. Stratton that she was giving a long distance treatment to a patient in another city, dissolving the patient's gallstones. [R., Vol. 2, pp. 255-256.]

Before summarizing the medical testimony in the case, we shall describe the facts which comprise the interstate transaction.

C. The Interstate Transaction.

Dr. Drown does business in Hollywood, California, under the fictitious name of Drown Laboratories. Mr. and Mrs. Edgar C. Rice resides at 13005 Greenwood Avenue, Blue Island, Illinois, a suburb of Chicago. On April 23, 1948, Dr. Drown examined Mrs. Rice at the Stevens Hotel in Chicago with one of the Drown instruments. Mrs. Rice complained of a lump in her breast. Her family doctor had examined her earlier that month, suspected a possible carcinoma, and suggested an immediate biopsy. [R., Vol. 1, pp. 40 and 50-51.] Dr. Drown concluded the lump was not a cancer but was caused by a

fungus growth that had spread through her digestive system into the liver. She recommended treatments with the Drown Radio Therapeutic Instrument by a Dr. John, who practiced and maintained his office in Chicago, Illinois. [R., Vol. 1, p. 37 and Vol. 7, p. 47.] Such treatments were given to Mrs. Rice directly and through "radio control" by Dr. John. In September of 1948, Dr. Drown again examined Mrs. Rice in Chicago and recommended continuation of the treatments. [R., Vol. 7, pp. 46-47.] Mrs. Rice received such treatments from Dr. John until she and her husband purchased the Drown instrument in question in October of 1948. [R., Vol. 1, p. 31.]

The firm with which Mr. Rice is employed has its offices in Los Angeles and in Chicago. His business takes him to Los Angeles frequently. On October 28, 1948, Mr. Rice while in Los Angeles personally went to the offices of the Drown Laboratories in Hollywood and there purchased a complete Drown Radio Therapeutic Instrument, Model No. 98 M, Serial No. 10264817, from Miss Zella Koerner, a sales representative of the Drown Laboratories. This instrument is in evidence as Exhibit 9. [See also R., Vol. 7, p. 50.] At the time of the purchase, Dr. Drown gave Mr. Rice a leaflet entitled "Drown Atlas," in evidence as Exhibit 3. This leaflet contained dial settings for the use of Mrs. Rice in treating herself with the Instrument. [R., Vol. 7, pp. 47-48; Vol. 1, p. 24.]

The invoice covering the sale of the Instrument by Drown Laboratories to Mr. Rice is in evidence as Exhibit 1. [See also R., Vol. 7, p. 48.] This invoice declares that the device was sold to Mr. Edgar Rice and sets forth his Blue Island, Illinois, address. The invoice

is marked "Paid" "By Z. K." In fainter writing, there appears the following: "O.K. R.B.D."

At the time of this purchase. Mr. Rice also obtained from the Drown Laboratories a copy of the circular which is in evidence as Exhibit 2. He and Mrs. Rice had obtained another copy of that circular on April 23, 1948, when Dr. Drown first examined Mrs. Rice at the Stevens Hotel in Chicago. [R., Vol. 7, p. 48.] This is the circular which contains most of the therapeutic and diagnostic claims made for the Drown instruments.

Mr. Rice then took the instrument [Ex. 9] and the literature which he obtained from the Drown Laboratories [Exs. 2, 3, and 10] back to Blue Island, Illinois, where his wife discontinued the treatments with Dr. John [R., Vol. 1, p. 31] and used this instrument to treat the lump in her breast, directly and through "radio control" for approximately one year. [R., Vol. 7, pp. 47-48.]

Thereafter, at the request of Mr. Rice, Dr. Drown made several diagnoses of Mrs. Rice by "remote control" —that is, while Dr. Drown was in Hollywood and Mrs. Rice was in Blue Island, Illinois. These diagnoses appear on charts which Dr. Drown mailed to the Rices, and which are in evidence as Exhibits 4 and 8. [R., Vol. 7, pp. 48-50; Vol. 1, p. 21.] Dr. Drown made an additional diagnosis of Mrs. Rice in Chicago on February 7, 1949. [Ex. 7; R., Vol. 7, p. 49.]

On March 9, 1949, Mr. Rice wrote a letter to Dr. Drown asking several questions, and by pre-arrangement with Dr. Drown, he left space after each question for the answer, which Dr. Drown then inserted, returning the letter and answers to him. [Ex. 5; R., Vol. 7, p. 49.] Dr. Drown stated that her long distance diagnosis of March 7, 1949, showed some improvement yet revealed

the presence of a new lump which she demonimated "congested lymphatic"; she declared that "the condition has never been cancerous but any lump can cause it if let go long enough without proper treatment"; she concluded by saying, "Mrs. Rice must realize if she is to get well she must swing her attention on to the work and put every effort forth to get well."

In August of 1949, Mr. Rice made a long distance call to Dr. Drown advising her that Mrs. Rice's condition appeared worse and asking for advice. [R., Vol. 7, p. 49.] Dr. Drown responded by letter dated August 3, 1949, now suggesting that Mrs. Rice have the breast removed [Ex. 6], although she had theretofore maintained there was no malignancy and no need for surgery. [R., Vol. 1, p. 53.]

D. The Medical Testimony.

Six witnesses, each of them an authority in a specialized field of medicine, testified on behalf of the Government regarding the merits of the Drown instruments. They were unanimous that these instruments are utterly worthless in the diagnosis or treatment of any disease.

Dr. Elmer Belt is a prominent surgeon and urologist of Los Angeles. He has been a member of the California State Board of Health for eight years, and was president of the Board for four years. [R., Vol. 1, pp. 105-106.] In his opinion, the Drown instruments [Exs. 9 and 11] are useless for the diagnosis or treatment of any disease condition. [R., Vol. 1, pp. 107-108 and 110-111.] "These things would be laughable if they were not so dangerous." ". . . to pretend to treat carcinoma of an organ after it has been recognized, by any hocus-

pocus method such as this endangers the life of the individual. It is well known that the only curative method for the treatment of cancer is usually a complete eradication of the cancer by surgery. To delay the treatment of cancer is equivalent to writing a sentence of death for the patient." [R., Vol. 1, p. 109.]

Dr. George W. Holmes is a physician and surgeon of Chicago, Illinois, specializing in thoracic surgery, which pertains to the chest, chest wall, lungs and heart. He is chief of the thoracic surgery service at Cook County Hospital in Chicago, which has 3500 beds, and he is also chief of thoracic surgery at the Hines Veterans Hospital, which has 3000 beds. [R., Vol. 2, pp. 265-266.]

Dr. Holmes began treating Mrs. Rice of Blue Island, Illinois, on January 31, 1951 [R., Vol. 2, p. 267], and treated her weekly or twice weekly up to August 25, 1951. [R., Vol. 2, p. 273.] Dr. Holmes' examination of Mrs. Rice revealed the presence of a lump in her breast and "much more." [R., Vol. 2, p. 274.] Upon objection of defense counsel, Dr. Holmes was prevented from testifying as to whether that condition is cancerous [R., Vol. 2, p. 272] or what that condition was in 1948.[1] [R., Vol. 2, p. 271.] He was permitted to state that at the time of the trial Mrs. Rice was physically unable to make the trip from Blue Island to Los Angeles for the purpose of testifying. [R., Vol. 2, p. 277.]

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[1]However, upon cross-examination by defense counsel, Mr. Rice stated that his wife's condition is malignant [R., Vol. 1, p. 59] but that medical doctors now advise against surgery because the shock would be too severe for the patient. [R., Vol. 1, pp. 55 and 62.] Cancer must be treated promptly if the patient is to be done any good, and "that is the reason for the trouble we are in . . . because we didn't have something done as soon as we discovered it. . . ." [R., Vol. 1, pp. 54-55.]

In the opinion of Dr. Holmes, the Drown Radio Therapeutic Instrument [Ex. 9] would be absolutely worthless for the treatment of any kind of disease or any kind of tumor. [R., Vol. 2, p. 361.]

Dr. Fred B. Moore is a physician and surgeon of Los Angeles, specializing in physical medicine. He is Professor of Therapeutics in the School of Medicine at the College of Medical Evangelists and is director of the School of Physiotherapy in the same institution. He is also Director of the Department of Physical Medicine at the White Memorial Hospital. Physical medicine is the use of physical agents such as water, light, electricity, and X-rays in the treatment of disease. [R., Vol. 2, pp. 278-279.]

In the opinion of Dr. Moore, the Drown instruments [Exs. 9 and 11] would have no therapeutic or diagnostic value whatever. [R., Vol. 2, pp. 279-287.]

Dr. Sol Baker is a physician in Los Angeles specializing in the diagnosis and treatment of cancer. He was associate director of the Department of Radiation Therapy at the Cedars of Lebanon Hospital. During the war, he was in the naval service as chief of the Department of Radiation Therapy, U. S. Marine Hospital in Baltimore. During the past 15 years, he has seen about 20,000 malignant tumors and between 80,000 and 100,000 non-malignant tumors. [R., Vol. 2, pp. 370-371.]

In Dr. Baker's opinion, the Drown Radio Therapeutic Instrument [Ex. 9] could not possibly eliminate a lump in the breast of any patient or prevent the development of cancer from such a lump. [R., Vol. 2, pp. 377-378.] Nor can the instrument in evidence as Exhibit 11 tune into the body, measure the function of its various parts,

or detect the presence of disease. [R., Vol. 2, pp. 378-379.]

Dr. James W. J. Carpender is a physician of Chicago, Illinois, specializing in the field of radiology. While with the Navy during the war, he was assistant chief of radiology at the National Naval Medical Center at Bethesda, Maryland. He also served on a hospital ship for almost two years as chief of radiology. He is now director of radiation therapy and associate professor of radiology at the University of Chicago. [R., Vol. 2, pp. 427-429.]

In the opinion of Dr. Carpender, the instrument in evidence as Exhibit 11 has no value whatsoever in the diagnosis of any human disease. [R., Vol. 2, pp. 429-430.] This opinion is based both upon his training and experience in the field of medicine and his personal observation of tests conducted upon a similar instrument at the University of Chicago, on December 31, 1949, by the defendant. [R., Vol. 2, pp. 430 and 435.] Defense counsel withdrew his objection to testimony describing these tests. [R., Vol. 2, pp. 432-433.]

The tests referred to were carried on by the defendant in the presence of representatives of the University. Samples of the blood of ten persons were obtained by the University, dried on small pieces of filter paper each of which was identified only by a number. The University retained a separate record regarding the known physical condition of each of these persons. [R., Vol. 2, pp. 435-436.]

The first blood sample selected was "No. 6." Dr. Drown placed this sample in her machine and operated the machine for about an hour. She concluded that the

patient had a Type IV cancer of the left breast with spread to ovaries, uterus, pancreas, gall bladder, spleen and kidney; that she was devoid of vision in her right eye; that her blood pressure was 107 over 71; that the ovaries were not producing ova; and that the following structures showed reduced function—pancreas, adrenal, pituitary, uterus, right ovary, parathyroid, spleen, heart, liver, gall bladder, kidneys, lungs, stomach, spinal nerves, intestines, ears, right eye. Records of the University showed that the patient had tuberculosis of the upper lobe of the right lung. [R., Vol. 2, pp. 435-436.]

With respect to the second blood sample, "No 10," Dr. Drown concluded the patient had dilated pulmonary veins, diseased heart valves, blood pressure of 127 over 80, normal function of both a uterus and a prostate gland, and low function in the following—pituitary, pulmonic and tricuspid valves, gall bladder, stomach, spleen, parathyroids, pancreas, and kidneys. Records of the University showed that the patient, a male, had a bleeding marginal ulcer secondary to gastro-enterostomy. His heart was normal. Dr. Carpender took the patient's blood pressure on two occasions on the afternoon when Dr. Drown conducted the tests. He testified that the pressure of the right arm on one occasion was 218 over 138 and on the other, 230 over 135. He also testified that the pressure of the left arm was 220 over 140 on one occasion, and 240 over 135 on the other. [R., Vol. 2, pp. 437-438.]

With respect to the third and last blood sample worked on by Dr. Drown, "No. 1," Dr. Drown reported that

the patient had an ischiorectal abscess, serious trouble with the prostate which was probably carcinoma with spread to urethra and the pelvic bones, loss or non-function of the left testicle, blood pressure of 166 over 78. Dr. Drown concluded that the prognosis or prediction of life expectancy in this patient was extremely poor. Records of the University showed that this patient was a healthy young male physician whose blood pressure was not elevated. Dr. Carpender did another physical examination on this person a year and nine months later, just before coming to Los Angeles to testify. He found no evidence of disease. [R., Vol. 2, pp. 438-439.]

The last Government witness, Dr. Homer C. Lawson, is associate professor of pharmacology at the University of Southern California, and assistant dean of the Medical School. He has carried out investigations in the behaviour of biological systems, and the reactions of organs and tissues. [R., Vol. 2, pp. 466-467.]

In the opinion of Dr. Lawson, the instrument in evidence as Exhibit 9 has no value or effect in the treatment of any disease. [R., Vol. 2, pp. 467-471.] The instrument in evidence as Exhibit 11 is incapable of tuning into the human body and its various parts, measuring their function, or detecting the presence of disease; it cannot record impinged nerves, count blood cells, analyze urine either in or out of the body, ascertain blood pressure or body temperature. [R., Vol. 2, pp. 471-474.] Nor is there any electrical magnetism emanating from the human body. [R., Vol. 2, pp. 474-476.]

III.

Statutory Provisions and Regulations Involved.

Federal Food, Drug, and Cosmetic Act:

"21 U. S. C. 352. Misbranded drugs and devices.

A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

* * * * * * *

(f) Unless its labeling bears (1) adequate directions for use . . . *Provided,* That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement."

"21 U. S. C. 331. Prohibited acts.

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

"*21 U. S. C. 333. Penalties—Violation of section 331.*

(a) Any person who violates any of the provisions of section 331 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine . . ."

Regulation of Federal Security Administrator:

"§1.101. *Drugs and devices; labeling, misbranding:*

(a) Among representations in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to another drug or device or a food or cosmetic." [21 Code of Federal Regulations (1949 Ed.), p. 12.]

IV.
Questions Involved.

(1) Did the defendant cause the device, which is in evidence as Exhibit 9, to be delivered for introduction into interstate commerce within the meaning of 21 U. S. C. 331(a)?

(2) Is the criminal information fatally defective in any respect?

(3) Did the trial court err in overruling the defendant's motion for an instructed verdict filed at the close of the Government's case?

(4) Did the trial court err in denying the defendant's motions with respect to a new trial and arrest of judgment?

V.
SUMMARY OF ARGUMENT.

A. The Defendant Caused the Device Which Is in Evidence as Exhibit 9 to Be Delivered for Introduction Into Interstate Commerce.

Appellant is in the business of manufacturing and selling "Drown Radio Therapeutic Instruments." Her place of business is in Hollywood, California, where she operates under the fictitious name of Drown Laboratories.

On October 28, 1948, appellant sold one of these instruments to Mr. Edgar C. Rice of Blue Island, Illinois, for the use of Mrs. Rice in treating herself at her home in Blue Island to eliminate a lump in her breast and prevent cancer from developing. Blue Island is a suburb of Chicago.

While the transaction in question was consummated on October 28, 1948, in Hollywood, appellant had a number of preliminary contacts with the Rices in Chicago during the preceding six months—diagnosing Mrs. Rice, recommending treatment with the "Drown Radio Therapeutic Instrument," and giving the Rices promotional literature regarding that instrument.

The invoice of sale states Mr. Rice's Blue Island, Illinois, address. It is clear from the surrounding circumstances that the parties contemplated what actually occurred—namely, that Mr. Rice would take the instrument back to his home where his wife would use it to treat herself in accordance with the directions appellant furnished Mr. Rice.

It was also contemplated by the parties that appellant would maintain "professional" supervision over Mrs.

Rice's progress, by direct personal contact when appellant was in Chicago, by correspondence with the Rices, and by long distance "radio" diagnoses from Hollywood.

During the following nine months, appellant did make direct and "radio" diagnoses of Mrs. Rice and did correspond with the Rices, giving additional directions for the use of the instrument and finally suggesting that Mrs. Rice have the breast with the lump removed.

Appellant was fully aware of the out-of-state destination and intended use of the device. When she caused its sale and delivery to Mr. Rice on October 28, 1948, she caused its "delivery for introduction into interstate commerce" within the meaning of 21 U. S. C. 331 (a). In *United States v. Sanders,* ..... F. 2d ..... (C. A. 10, May 7, 1952) (opinion appears as Appendix A of this brief), the Court of Appeals for the Tenth Circuit so held on similar facts.

Such a holding gives meaning to the plain language of the statute and is consistent with the liberal construction the Courts have given the Federal Food, Drug, and Cosmetic Act to protect the consumer and prevent misuse of the channels of interstate commerce.

Congress has ample power under the commerce clause to regulate transactions such as the one in question.

B. The Criminal Information Is Not Fatally Defective in Any Respect.

Appellant argues that there are a number of defects in the Information. Under Criminal Rule 12(b)(2), such matters must be raised by motion before trial. No such motion was made.

In addition to being untimely, appellant's assertion is without merit.

The Information, far from being inadequate, follows Form 11 of the Appendix of Forms of the Federal Rules of Criminal Procedure, pleading all of the facts required by that Form and much more.

The Information describes the instrument in question with considerable particularity. While appellant now professes to be uncertain as to the instrument and transaction referred to by the Information, she had no difficulty in identifying and stipulating to the instrument and transaction in the lower court.

Appellant's contention that the device is harmless and therefore should be exempted from the requirements of 21 U. S. C. 352 (f) (1) is doubly fallacious. An inert device is dangerous if relied upon by a person suffering from a serious ailment. A worthless device is not harmless if its use lulls a victim into postponing competent treatment for a disease like cancer. Moreover, 21 U. S. C. 352 (f) does not contemplate that a device should be exempted from bearing adequate directions for use in its labeling merely because it is harmless.

At any rate, it is settled that statutory exceptions are matters of defense, constitute no part of the necessary description of the offense, and need not be negatived by the Government in its pleadings.

The Information is not "redundant and multifarious" by reason of its inclusion of certain charts and letters in describing the "labeling" of the device, though such charts and letters were not written until after the sale of the device. It is settled that literature need not physically accompany a device during its interstate journey to com-

prise its "labeling" where, as here, the literature and the device are part of an integrated transaction. Furthermore, appellant stipulated that such charts and letters are "labeling."

The Information is not duplicitous. It was proper to charge that the device sold to Mr. Rice was misbranded in that its labeling contained (1) false and misleading *therapeutic* claims about that device, and (2) false and misleading *diagnostic* claims about another device. The statute condemns labeling that is false or misleading "in any particular."

C. The Trial Court Did Not Err in Overruling the Defendant's Motion for an Instructed Verdict.

Defendant filed a Motion for Instructed Verdict at the close of the Government's case. The Motion was denied, and the defendant then offered its evidence comprising 525 pages of testimony. Defendant thereby waived the Motion and since she did not renew it at the close of all the evidence, it need not be considered on appeal.

In any event, the Motion was without merit and was properly denied by the Court below.

The informed opinion testimony of persons highly qualified in the fields of medicine, engineering, and physics is substantial evidence. The Government relied not only upon such testimony but also upon the demonstrated inefficacy of the devices (1) in the case of Mrs. Rice and (2) in the tests which the defendant herself conducted at the University of Chicago, as described by Dr. Carpender.

The Government's evidence overwhelmingly establishes that the Drown devices are absolutely worthless in the diagnosis or treatment of any disease condition.

By introducing defendant's labeling to establish what claims were made for the devices, the Government obviously did not thereby establish the *truth* of those claims.

The credibility of witnesses is a matter for the jury. Witnesses for the Government were not prejudiced against the defendant because she is a chiropractor. Although a number of the Government's witnesses were physicians, there was no prejudice against the defendant on that account and, in fact, one of the first Government witnesses, the Secretary of the California State Board of Chiropractic Examiners—like appellant, himself a chiropractor—testified the Board had examined one of the Drown devices in question and concluded it was worthless.

D. The Trial Court Did Not Err in Denying Defendant's Motions With Respect to a New Trial and Arrest of Judgment.

Defendant's motions for a new trial and in arrest of judgment were filed 28 days after verdict and were not based on newly discovered evidence. Under Criminal Rules 33 and 34, these motions came too late.

In denying these motions, the trial court not only did so on jurisdictional grounds but also pointed out that defendant had had a fair trial and there was no basis on which to justify setting aside the verdict of the jury.

VI.

ARGUMENT.

A. The Defendant Caused the Device Which Is in Evidence as Exhibit 9 to Be Delivered for Introduction Into Interstate Commerce.

In section C of our Statement of the Facts, *supra,* we discussed rather fully the facts which comprise the interstate transaction in this case. The essential and undisputed elements include the following:

(1) The defendant resides in Hollywood, California, and does business there under the fictitious name of Drown Laboratories.

(2) The purchaser of the Drown radio therapeutic instrument [Ex. 9], Mr. Edgar C. Rice, and his wife, the intended user of the instrument, reside in Blue Island, Illinois, and this fact was known to the defendant at the time of the purchase in question.

(3) The defendant first met and diagnosed Mrs. Rice in Chicago, Illinois, on April 23, 1948. The defendant then suggested that Mrs. Rice obtain treatments in Chicago from a disciple of hers, a Dr. John, who used one of the defendant's radio therapeutic instruments. Defendant at the same time in Chicago also furnished the Rices with a copy of the circular, in evidence as Exhibit 2, which contains most of the fantastic therapeutic and diagnostic claims in question, and which may properly be considered one of the important factors that eventually induced the Rices to purchase the device that is Exhibit 9.

(4) Four months later, in September of 1948, the defendant again examined Mrs. Rice at Chicago and recommended continuation of the treatment with the Drown instrument.

(5) The following month, the Rices decided to buy a Drown instrument for Mrs. Rice's use in treating herself at her home in Blue Island, Illinois. Mr. Rice, in Los Angeles on a business trip, went to the defendant's place of business—the Drown Laboratories—at Hollywood on October 28, 1948. There he conferred with both the defendant and with Zella Koerner, a sales representative of the defendant. Miss Koerner handled the mechanics of selling the machine to the defendant, such as preparing the invoice of sale, collecting the money, and giving Mr. Rice a receipt. Mr. Rice also obtained another copy of the circular, Exhibit 2. The defendant, in addition to approving the sale [see Ex. 1], took care of the "professional" aspects of the transaction (1) by preparing a leaflet of instructions [Ex. 3] explaining how Mrs. Rice should use the instrument in treating herself, and (2) by giving that leaflet to Mr. Rice.

(6) The invoice of sale [Ex. 1] is a printed form bearing the heading "Drown Laboratories, Manufacturers of Drown Radio Therapy and Radio Vision Instruments, 7509 Sunset Boulevard, Hollywood, Calif." It describes the instrument and gives its model number, serial number, sales price, and tax. It also declares that the instrument was sold to "Mr. Edgar Rice, 13005 Greenwood Ave., Blue Island, Illinois."

(7) As contemplated by the parties to this transaction, Mr. Rice then took the instrument back to his home in Blue Island, Illinois, for the use of his wife, who thereupon discontinued taking treatments from Dr. John and began self-treatments with this instrument in her home, directly and by "radio" control. [R., Vol. 7, pp. 47-48; Vol. 1, pp. 26-27, and 31.]

(8) Subsequently, the defendant corresponded with the Rices, made diagnoses of Mrs. Rice by long distance "radio" control, and sent directions for Mrs. Rice's further self-treatment in her home in Illinois with the device Mr. Rice had purchased. [Exs. 4, 5, 6, 7, and 8; R., Vol. 7, pp. 48-50.]

From the foregoing summary, it is clear that the defendant herself stimulated the interest of the Rices in the purchase of the Drown radio therapeutic instrument for Mrs. Rice's use at her home in Blue Island, Illinois. Both by her personal advice and through her circular, Exhibit 2, defendant led them to believe that her instrument had miraculous healing power.

It is immaterial that the clerical aspects of the sale were handled by her sales representative, Zella Koerner. In *United States v. Dotterweich,* 320 U. S. 277 (1943), the Supreme Court held that a corporate officer could be found criminally responsible for the corporation's interstate shipments of violative drugs though he had no personal connection with the shipments.[2] On page 284, the Court observed:

> "Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial . . . The offense is committed . . . by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs. Hardship there doubtless may be

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[2]For a fuller statement of the facts, see the opinion of the Court of Appeals, *United States v. Buffalo Pharmacal Co., Inc., and Dotterweich,* 131 F. 2d 500, 501 (C. A. 2, 1942).

> under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless."

See also *United States v. Parfait Powder Puff Co., Inc.*, 163 F. 2d 1008 (C. A. 7, 1947), cert. den. 332 U. S. 851. In the instant case, the defendant *was* personally and intimately connected with the transaction, some of the details of which were handled by her sales representative acting in the name of "Drown Laboratories"—the fictitious name under which the defendant does business.

However, defendant's main argument is that since Mr. Rice bought the instrument at her place of business in Hollywood, the transaction was wholly intrastate within the State of California. The complete and most persuasive answer to this argument is the recent opinion of the Court of Appeals for the Tenth Circuit in *United States v. Sanders*, ... F. 2d ..... (May 7, 1952), rejecting an identical defense argument. Since that opinion is on all fours with this phase of the instant case and since it has not yet been reported, we are including it verbatim in our brief as Appendix A.

The *Sanders* case was a criminal contempt proceeding charging the defendant with violating an injunction which restrained him from shipping a misbranded drug in interstate commerce. Following the issuance of the injunction, Sanders sold his misbranded drug only to customers who came to his place of business in Oklahoma, and he deliv-

ered the drugs to them there. He was charged with violating the injunction by making six such sales and deliveries to out-of-state customers who, he knew, intended to return to their homes in the other States with the drugs. Sustaining the Government's position, the Court said in part:

> "As stated by the Supreme Court in United States v. Walsh, 331 U. S. 432, 434, 'The Federal Food, Drug, and Cosmetic Act rests upon the constitutional power resident in Congress to regulate interstate commerce. To the end that the public health and safety might be advanced, it seeks to keep interstate channels free from deleterious, adulterated and misbranded articles of the specified types. * * * It is in that interstate setting that the various sections of the Act must be viewed.' The Act must be given a reasonable construction to effectuate its salutary purposes. *It prohibits not only the introduction into interstate commerce of adulterated articles but also the delivery thereof for introduction into interstate commerce. One is as much a violation of the Act as the other* . . . The decisions . . . make it clear that whether delivery for transportation is made to a common carrier, a private carrier, or even to the purchaser for transportation by himself is immaterial.
>
> "To be guilty of violating the Act, it was not necessary that appellee be engaged in interstate commerce with respect to a misbranded drug. It was sufficient if he was engaged *in delivering such a drug for introduction into interstate commerce.*" (Emphasis added.)

By this decision, the Court gave meaning to each word in the statutory prohibition of 21 U. S. C. 331 (a):

> "The introduction or delivery for introduction into interstate commerce . . ."

The defendant's construction of this statute would erase the words "or delivery for introduction." It is fundamental that the Courts will strive to construe legislation so as to give full significance to every word. *Ginsberg & Sons, Inc. v. Popkin,* 285 U. S. 204, 208 (1932). Speaking of this Act, the Supreme Court observed in *United States v. Dotterweich,* 320 U. S. 277, 280 (1943):

> "The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words."

In construing the jurisdictional scope of the Federal Food, Drug, and Cosmetic Act, the Courts have consistently recognized the Congressional design to give maximum protection to the ultimate purchaser through the broadest constitutional regulation of interstate commerce.

The giving of a guaranty falsely assuring that a drug is not in violation of the Federal Food, Drug, and Cosmetic Act is prohibited by the Act though the drug has not been shipped interstate. *United States v. Walsh,* 331 U. S. 432, 437 (1947). "By this means, some of the evils which Congress sought to eliminate are cut down at their source and the effectiveness of the Act's enforcement is greatly enhanced."

Causing articles to become misbranded after they have moved in interstate commerce is in violation of the Act "without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had received the articles at the end of the

interstate shipment." *United States v. Sullivan,* 332 U. S. 689, 696 (1948).

A device that is misbranded when introduced into and while in interstate commerce is subject to seizure and condemnation under the Act at any time thereafter, even in the home of the purchaser. *United States v. Olsen,* 161 F. 2d 669, 671 (C. A. 9, 1947), cert. den. 332 U. S 768.

A food that is manufactured and sold within the same State is subject to seizure and condemnation if it contains an adulterated ingredient of an interstate source. *United States v. Allbrook Freezing & Cold Storage, Inc.,* 194 F. 2d 937, 939 (C. A. 5, 1952).

As the Supreme Court pointed out in *United States v. Urbuteit,* 335 U. S. 355, 357-358 (1948):

> "The Act is not concerned with the purification of the stream of commerce in the abstract. The problem is a practical one of consumer protection, not dialectics."

See also *Kordel v. United States,* 335 U. S. 345, 351 (1948).

It is clear from the legislative pattern that the Act contains a comprehensive scheme of regulation in which no "loopholes" are to be tolerated. [See 21 U. S. C. 331 (a), (b), (c), (k), and 334 (a)]. Nor will the Courts lightly open "an escape valve" that will nullify the beneficent purpose of the law. *Alberty Food Products v. United States,* 194 F. 2d 463, 464 (C. A. 9, 1952).

Basic concepts regarding Congressional authority need little amplification. The power of Congress to regulate interstate commerce is plenary in scope, may be exercised to its utmost extent, and acknowledges no limitations other than are prescribed in the Constitution. *Gibbons v. Og-*

den, 9 Wheat. 1, 196 (1824); *Second Employers' Liability Cases,* 223 U. S. 1, 47 (1912). It is no objection to the exertion of the power that its exercise is attended by the same incidents which attend the exercise of the police power of the States. *United States v. Carolene Products Co.,* 304 U. S. 144, 147 (1938).

The power under the commerce clause extends to every instrumentality or agency by which interstate commerce is carried on; and the full control by Congress of the subjects committed to its regulation is not to be denied or thwarted by the commingling of interstate and intrastate operations. *The Minnesota Rate Cases,* 230 U. S. 352, 399 (1913). It extends to those activities intrastate which so affect interstate commerce, or the exertion of the power of Congress over it, as to make regulation of them appropriate means to the attainment of a legitimate end, the effective execution of the granted power to regulate interstate commerce. *United States v. Wrightwood Dairy Co.,* 315 U. S. 110, 119 (1942); *National Labor Relations Board v. Fainblatt,* 306 U. S. 601, 605-606 (1939). The power includes the ability to deal with a host of acts which are not in themselves interstate commerce but, because of their relation to and influence upon interstate commerce, come within the power of Congress. *United States v. Ferger,* 250 U. S. 199, 203 (1919); *Weiss v. United States,* 308 U. S. 321, 327 (1939). Note *Brooks v. United States,* 267 U. S. 432 (1925). Congress may adopt not only means which are necessary, but those which are convenient, to the exercise of the commerce power, *Seven Cases v. United States,* 239 U. S. 510, 515 (1916), and may itself determine the means appropriate for this purpose. *McDermott v. Wisconsin,* 228 U. S. 115, 128 (1913). Transportation is not the exclusive test of the

scope of congressional authority under the commerce clause. *Chicago & N. W. Ry. Co. v. Bolle,* 284 U. S. 74, 78 (1931); *Dahnke-Walker Milling Co. v. Bondurant,* 257 U. S. 282, 291 (1921).

Congress may not only prevent the interstate transportation of a proscribed product but may also "stop the initial step toward (such) transportation, (namely) production with the purpose of so transporting it. *United States v. Darby,* 312 U. S. 100, 117 (1941).

Nor is the place of sale or the passage of title material. In *N. L. R. B. v. Levaur,* 115 F. 2d 105, 108-109 (C. A. 1, 1940), cert. den. 312 U. S. 682, the Court said:

> "It is not in the least significant that the sales are so made that title passes to the purchaser within Rhode Island. It has long been held that a sale involving interstate transportation is not removed from Congressional regulation because the sale itself is intrastate, either before or after the transportation." (Citing authorities.)

See also *Barnes v. United States,* 142 F. 2d 648, 651 (C. A. 9, 1944) and *Arner Co., Inc. v. United States,* 142 F. 2d 730, 733-734 (C A. 1, 1944), cert. den. 323 U. S. 730. "The Act is concerned not with the proprietory relation to a misbranded or an adulterated drug but with its distribution." *United States v. Dotterweich,* 320 U. S. 277, 283 (1943).

A situation closely analogous to the instant case arose in an injunction suit under the Fair Labor Standards Act in *Tobin v. Grant,* 79 Fed. Supp. 975 (N. D. Calif., 1948). Defendants in California manufactured bank books, check books, and union membership books, as well as book covers. On the books and covers, defendants embossed the

names and out-of-state addresses of the organizations for whose use they were designed. Defendants then delivered these books and covers to their customers in California who thereafter shipped them to the out-of-state organizations whose names and addresses appeared thereon. The statutory provision there involved declared in part that no person "shall ship or deliver for shipment in commerce . . ." In the carefully considered opinion of Judge Harris, the contentions of the defendants there, similar to those raised here, were rejected:

Pages 976-977

> "Defendants argue that knowledge of the ultimate destination of their product is immaterial. They claim that the manner of consummating their sales, with title passing to an intrastate purchaser, is controlling.
>
> "When title passed is entirely irrelevant. (Citing cases.) Rather, the Court must ascertain whether articles were delivered in California for shipment in interstate commerce. Patently, they were—as their ultimate destination was made manifest from the clear imprint on the articles.
>
> "Defendants have assumed to place some significance in the fact that the articles were not delivered to a carrier and argue, therefore, that the manufactured products were not delivered for shipment. Delivery to a carrier is not the test. (Citing authorities.)"

See also *United States v. Simpson,* 252 U. S. 465 (1920).

Appellant cites a number of cases dealing with the power of states to tax particular types of transactions apparently in an effort to establish that the instant trans-

action is beyond the power of Congress to regulate interstate commerce. But the Supreme Court has warned on a number of occasions that merely because the Court upholds the validity of a state taxing statute as not imposing an undue burden on interstate commerce, it does not follow that the transaction to which the tax is applied "is beyond the scope of interference by Congress in cases where such interference is deemed necessary for the protection of commerce among the States." *Swift and Company v. United States,* 196 U. S. 375, 400 (1905); *Minnesota v. Blasius,* 290 U. S. 1, 8 (1933); *Stafford v. Wallace,* 258 U. S. 495, 525 (1922); *Board of Trade of the City of Chicago v. Olsen,* 262 U. S. 1, 33 (1923).

Defendant argues that the sale to Mr. Rice was an isolated transaction and that "the evidence shows from the stipulation of facts she was not in the business any way of selling such instruments, either locally or otherwise." (App. Op. Br. p. 32, line 16) Even if this assertion were true—and it is not since there is no such stipulation—, it would be of no comfort to defendant, for the statutory prohibition against the delivery of a misbranded device for introduction into interstate commerce (21 U. S. C. 331 (a)) is not qualified by a requirement that the Government prove such delivery was one of a series or part of the regular conduct of a business. *Every* such delivery is prohibited.

Actually, the Record here plainly reflects that the defendant *was* engaged in the business of selling her instruments. The invoice of sale [Ex. 1] is made out on a printed form which obviously contemplates repeated sales of Drown instruments. Thus, the invoice refers to defendant's business as "Manufacturers of Drown Radio Therapy and Radio Vision Instruments"; it calls for the

insertion of information always associated with sales on a substantial scale such as order number (in this case, No. 177), customer's number, identity of salesman, terms of sale, quantity, model number, serial number, warranty and disclaimer, etc. The printed Exhibits 2 and 3 are additional strong evidence of sales promotional activity. Also noteworthy is the fact that the defendant employed a *sales representative,* Zella Koerner, to handle the details of sales of her instruments. [R. Vol. 7, p. 47.] Furthermore, Dr. John of *Chicago, Illinois,* gave treatments on a Drown instrument to Mrs. Rice. [R., Vol. 7, pp. 47 and 51.]

We submit, and the Record amply confirms, that the defendant was fully cognizant of the out-of-State destination and use of Exhibit 9, and that she caused said device to be delivered for introduction into interstate commerce.

B. The Criminal Information Is Not Fatally Defective in Any Respect.

Appellant's assertion that the Information is defective in a number of respects is without merit and comes too late. (App. Op. Br. pp. 39-48.) Criminal Rule 12 (b) (2) requires that such defenses and objections be raised only by motion before trial. (See *Cratty v. United States,* 163 F. 2d 844, 849 (D. C. Apps., 1947).) No such motion was made.

The first alleged defect is that the Information does not state how or in what manner the unlawful act was done. Form 11 of the Appendix of Forms approved by the Supreme Court in adopting the Federal Rules of Criminal Procedure is entitled "Information for Food and Drug

Violation." A comparison of Form 11 with the Information filed in this case [R., Vol. 7, p. 2] establishes that the Government pleaded every element which the Supreme Court has deemed essential, and much more. The Information contains a description of the unlawful act, the time it transpired, the device in question, the labeling, and the multitude of respects in which the device was misbranded. Plainly, no more is needed.

Appellant's complaint that the device is not sufficiently described is difficult to understand since the Information specifies its name, model number, and serial number. [R., Vol. 7, p. 2.] This data corresponds with the Stipulation as to Facts [see R., Vol. 7, pp. 47-48, and Ex. 1] where defendant had no difficulty in identifying and stipulating to the device and transaction in question.

Nor is there any merit to the argument that it is improper to plead that a "device" is misbranded, and that the pleading should be in the language of the statutory definition of the term "device." Form 11 uses the word "food"; if it were couched in the language of the statutory definition of the term "food" (21 U. S. C. 321(f)), it would say "articles used for food." See also the definitions of drug and cosmetic. (21 U. S. C. 321(g) and (i).) And the cumbersome pleading suggested by appellant would moreover violate the requirement that the information "shall be a plain, concise and definite written statement of the essential facts constituting the offense charged." (Criminal Rule 7(c).)

With respect to the violation of 21 U. S. C. 352(f)(1) charged in the Information, appellant's contention is again without merit. That section declares that a drug or device is misbranded unless its labeling bears adequate directions for use. The section further directs the

Federal Security Administrator to promulgate regulations exempting drugs and devices from having adequate directions for use in their labeling if not necessary for the protection of the public health. The Administrator has promulgated such regulations, specifying the conditions under which a drug or device may be so exempt. (21 Code of Federal Regulations (1949 Ed.) Sec. 1.106(b)-(k), pp. 17-18.)

Appellant's argument on this point is difficult to follow. First it is said that the use of the instrument in question "could not possibly harm any human being." (App. Op. Br. p. 44, line 24.) The harm done to Mrs. Rice belies this statement. See also the testimony of Dr. Elmer Belt. [R., Vol. 1, p. 109.] And in *Ewing v. Mytinger & Casselberry,* 339 U. S. 594, 600 (1950), the Supreme Court said:

> ". . . public damage may result even from harmless articles if they are allowed to be sold as panacease[3] for man's ills . . . For all we know, the most damage may come from misleading or fraudulent labels." (Footnote added.)

See also *United States v. Kordel,* 164 F. 2d 913, 916-917 (C. A. 7, 1948), affirmed 335 U. S. 345. Pertinent here is an observation made by the Court in *United States v. 6*

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[3]Here, defendant's labeling declares: "We do not claim our method of treatment to be a panacea. There are some conditions which no known therapy has been able to control. *We do claim, however, that this instrument far surpasses any other known method of diagnosis or therapy,* because it uses natural methods and because those methods have a scientifically accurate foundation." [Ex. 2—emphasis added.]

Devices, "Electreat Mechanical Heart," 38 Fed. Supp. 236, 238 (W. D. Mo., 1941):

> "From a practical standpoint, the benefit to be derived from the use of the instrument was tersely stated by one of the several leading physicians of Kansas City, to be that the use of the instrument would not injure one if there was nothing the matter with him, but that if a person was suffering from any disorder or ailment its use might and probably would be injurious."

Upon the fallacious premise that the device is harmless, appellant then seems to assert that it should have been exempted by the regulations from bearing adequate directions for use in its labeling, and that somehow this comprises a defect in the Information. But there is no statutory mandate directing the Administrator to exempt all harmless drugs and devices, or to refuse exemption to articles that are not harmless. See *Alberty Food Products v. United States,* 194 F. 2d 463, 464 (C. A. 9, 1952). The statutory criterion is whether adequate directions for use in the labeling are "necessary for the protection of the public health." Thus the regulations deem such directions unnecessary even with respect to *potent* drugs and devices if the articles are to be dispensed upon the prescription of a physician.[4] (See *United States v. El-O-Pathic Pharmacy,* 192 F. 2d 62, 74-75 (C. A. 9, 1951).)

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[4]Legislative ratification of this viewpoint appears in recent Congressional action amending the Act to tighten the controls over drugs which should be dispensed on prescription only. [Public Law 215, 82d Cong., Ch. 578, 1st Sess., H. R. 3298, approved October 26, 1951.] This amendment defines the categories of drugs that must be sold on prescription only, and expressly exempts such drugs from bearing adequate directions for use in their labeling.

If a device comes within the exemption regulations, that is a matter of affirmative defense which must be raised and proved by the defendant. *Ocean Accident & Guaranty Corp. v. Rubin,* 73 F. 2d 157, 166 (C. A. 9, 1934), 96 A. L. R. 412; *McKelvey v. United States,* 260 U. S. 353, 357 (1922); *People v. Fowler,* 84 P. 2d 326, 329-330 (Appellate Dept. Sup. Ct., L. A. County, Calif., 1938). For a well-considered opinion applying this principle and holding that certain devices did not comply with the exemption regulations, see *United States v. 22 Devices . . . Halox Therapeutic Generator,* 98 Fed. Supp. 914 (S. D. Calif., 1951).

It is settled that statutory exceptions are matters of defense, constitute no description of the offense, and need not be negatived by the Government in its pleadings. *McKelvey v. United States,* 260 U. S. 353, 356-357 (1922); *Frederick v. United States,* 163 F. 2d 536, 544 (C. A. 9, 1947), cert. den. 332 U. S. 775.

Another contention of appellant is that the Information is "redundant and multifarious." Defendant appears to be arguing that the Information improperly describes certain circulars, letters, and charts as "labeling," since some of that material (charts and letters) was not in existence at the time when the device was sold to Mr. Rice. But it was *stipulated* that all of this material was part of the labeling of this device. [R., Vol. 7, pp. 48-50.] Moreover, it is settled that literature need not physically accompany a drug or device during its interstate journey in order to comprise "labeling" within the meaning of 21 U. S. C. 321(m)(2). See *Kordel v. United States,* 335 U. S. 345 (1948), sustaining a holding that booklets shipped a year and a half after certain

drugs constituted the "labeling" of the drugs since they were, as here, part of an integrated transaction.

Appellant also seems to be asserting that the Information is duplicitous because it charges the device sold to Mr. Rice was misbranded in that its labeling contained (1) false and misleading *therapeutic* claims about that device, and (2) false and misleading *diagnostic* claims about another device. The pertinent statute reads:

21 U. S. C. 352

"A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading *in any particular.*" (Emphasis added.)

An interpretive regulation of the Federal Security Administrator adopted under authority of 21 U. S. C. 371(a) reads:

21 C. F. R. (1949 Ed.) Sec. 1.101 (p. 12):

"Drugs and devices; labeling, misbranding

(a) Among representations in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to *another* drug or device or a food or cosmetic." (Emphasis added.)

The statutory language "in any particular" is broad and unqualified. If the labeling of a device makes false and misleading claims about that device *and* about another device, the Government may predicate its charges upon all such claims. See *United States v. 95 Barrels . . . Apple Cider Vinegar,* 265 U. S. 438, 442-443 (1924), where the Supreme Court said with reference to an iden-

tical provision in the Federal Food and Drugs Act of 1906:

> "The statute is plain and direct. Its comprehensive terms condemn *every* statement, design and device which may mislead or deceive." (Emphasis added.)

During the trial, defendant made no objection to the introduction of the *diagnostic* device referred to [Ex. 11] or to the extensive testimony relating to such device.[5]

Nor is there any valid objection to stating in one count the various modes in which the device [Ex. 9] was misbranded. See *Crain v. United States,* 162 U. S. 625, 636 (1896); *Frederick v. United States,* 163 F. 2d 536, 544 (C. A. 9, 1947), cert. den. 332 U. S. 775.

We submit that the rule laid down by this Court in *Woolley v. United States,* 97 F. 2d 258, 261 (C. A. 9, 1938), cert. den. 305 U. S. 614, was fully complied with in this case:

> "It is not necessary that an indictment set forth a myriad of detail, or that it satisfy every objection which human ingenuity can devise. It is enough if it charges every substantial element of the offense and at the same time apprises the accused of the charge against him in such manner that he can prepare his defense without being taken by surprise, and that he have the assurance that he will be protected against another prosecution for the same offense."

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[5]At one point, defense counsel did object to a particular line of inquiry upon some ground remote from what is now urged here, and then in effect withdrew his objection. [R. Vol. 2, pp. 430-433.]

C. The Trial Court Did Not Err in Overruling the Defendant's Motion for an Instructed Verdict.

At the close of the Government's case, the defendant filed a Motion for Instructed Verdict. [R., Vol. 7, p. 16.] This Motion was denied by the trial court. [R., Vol. 3, p. 499.] No similar motion was made at the close of all the evidence. Defendant, by offering evidence after the motion was denied and not renewing the motion at the close of all the evidence, effectively waived that motion so that it need not be considered on appeal.[6] *Mosca v. United States,* 174 F. 2d 448, 450-451 (C. A. 9, 1949).

Nevertheless, an examination of that motion shows it to be without merit. A motion for a judgment of acquittal is directed to the sound discretion of the trial court and will not be disturbed in the absence of a showing of abuse of discretion. *Ng Sing v. United States,* 8 F. 2d 919, 920 (C. A. 9, 1926). On such a motion, it is well established that the evidence must be considered in the light most favorable to the party against whom it is urged, and that the motion will be denied if substantial evidence has been introduced sufficient to take the case to the jury. *Garber v. United States,* 145 F. 2d 966, 969 (C. A. 6, 1944).

Appellant is in error in stating that her Motion for Instructed Verdict raised the jurisdictional question.

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[6]The 525 pages of defense testimony—*e. g.,* pages 499-1024 of the Reporter's Original Transcript of Proceedings—have been certified to this Court pursuant to appellant's initial designation, but were not designated by appellant as material to the appeal. [R. Vol. 7, pp. 43-44.]

(App. Op. Br. p. 48, line 13.) In fact, the Motion itself gives the following as a ground for a directed verdict [R., Vol. 7, pp. 16-17]:

> "Because the Government has failed to prove its case, beyond a reasonable doubt, in any particular charged in the information, *except the stipulation with reference to the introduction, or delivery for introduction, into interstate commerce, the device complained of by the government,* and said stipulation of itself not being sufficient to be the basis of a verdict of 'guilty,' without the government having proved, beyond a reasonable doubt, that said device was misbranded *at the time of said stipulated introduction or delivery for introduction, into interstate commerce.*" (Emphasis added.)

Thus, the Motion speaks of a "stipulated introduction or delivery for introduction into interstate commerce."

A considerable part of the Government's medical and physical testimony was based upon the informed opinion of highly qualified persons. Defendant's Motion seems to argue that such testimony is insubstantial. However, it is settled that such testimony is substantial. *Reilly v. Pinkus,* 338 U. S. 269, 274 (1949); *Research Laboratories, Inc. v. United States,* 167 F. 2d 410, 416-417 (C. A. 9, 1948), cert. den. 335 U. S. 843; *United States v. One Device, Intended For Use As A Colonic Irrigator,* 160 F. 2d 194, 199 (C. A. 10, 1947). Moreover, much of the Government's testimony dealt with the demonstrated inefficiency of this device to eliminate the lump in Mrs. Rice's breast and to prevent cancer therefrom. In addition, the testimony of Dr. Carpender described actual tests that were conducted by the defendant herself at the University of Chicago.

The shotgun nature of the Motion for Instructed Verdict challenges the Government's proof with respect to each *therapeutic*[7] claim alleged to be false and misleading. We submit that the Government's physical and medical testimony, summarized earlier in this brief, overwhelmingly establishes that the Drown devices are absolutely worthless in the diagnosis or treatment of *any* disease condition, though it may be noted that it is not incumbent upon the Government to prove that each of the therapeutic and diagnostic claims is false and misleading; such proof regarding any one of them is sufficient. *United States v. One Device, Intended For Use As A Colonic Irrigator,* 160 F. 2d 194, 200 (C. A. 10, 1947); see also *Crain v. United States,* 162 U. S. 625, 636 (1896); *Frederick v. United States,* 163 F. 2d 536, 544 (C. A. 9, 1947), cert. den. 332 U. S. 775.

Still discussing the Motion for Instructed Verdict, appellant raises a curious argument, contending that the "case histories" set forth in her circular, which is Exhibit 2 in evidence, are "positive proof of the claims of appellant that said device does treat efficaciously such diseases and infirmities." (App. Op. Br. p. 55, line 7.) Such "case histories" provide the basis for most of the claims which the Information alleges are false and misleading. The circular was introduced into evidence for the purpose of establishing that such claims were actually made in defendant's labeling. To say that the introduction of the evidence establishing the claims alleged to be false, automatically establishes the truth of such claims is, we submit, to state an absurdity. Under such circumstances,

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[7]The Motion is silent with respect to the *diagnostic* claims which the Information charges are false and misleading.

there could never be a successful proceeding against any nostrum and defendants could act with impunity behind the sheltering cover of testimonials, "case histories," and "the doctors say." See *United States v. John J. Fulton Co.,* 33 F. 2d 506, 507 (C. A. 9, 1929).

In passing, defendant makes reference to the Government's medical witnesses as members of the American Medical Association, declaring that they were prejudiced against the defendant presumably because she is a chiropractor. (App. Op. Br. p. 56, line 18.) So unwarranted an inference would not be ground for relief here in any event, such matters being determined by the jury under appropriate instructions. See *Barone v. United States,* 94 F. 2d 902, 903 (C. A. 9, 1938). But it is worthy of note that one of the first Government witnesses was Dr. Willard W. Percy, D. C., secretary of the California State Board of Chiropractic Examiners, who testified that the Board had examined one of the defendant's devices in question and concluded it was worthless. [R., Vol. 1, pp. 63-85.]

We submit that the Motion for Instructed Verdict was properly denied by the District Court without any abuse of discretion, and that the Motion was subsequently waived.

D. The Trial Court Did Not Err in Denying the Defendant's Motions With Respect to a New Trial and Arrest of Judgment.

The jury's verdict of guilty was brought in on September 24, 1951 [R., Vol. 7, p. 23.] On October 22, 1951, defendant filed a Motion for a New Trial. [R., Vol. 7, p. 25.] This Motion was not based on any newly discovered evidence. [R., Vol. 5, p. 1118.]

On October 22, 1951, defense counsel also asked he be given permission to file a motion in arrest of judgment a week later. [R., Vol. 5, p. 1118.]

Also on October 22, 1951, defense counsel asked for permission to file *"nunc pro tunc"* a motion for a new trial and a motion in arrest of judgment.

All of these motions were denied by the lower court which observed [R., Vol. 5, pp. 1119-1120]:

> "She had a long trial. It was before a jury. The defendant certainly was represented by competent counsel. We leaned over backwards to allow her to introduce certain evidence—in fact, the District Attorney many times thought we were too lenient in allowing her to introduce the testimony she wanted to introduce. She got a fair hearing, she got a fair trial, and the jury rendered its verdict. There is nothing in the world, as far as I know, to justify setting aside the verdict, ignoring the verdict of the jury."

The Court also remarked it doubted it had "any jurisdiction to grant either one of these motions" because they were made after the time permitted by the Federal Rules of Criminal Procedure. [R., Vol. 5, p. 1119.]

Motions for a new trial are governed by Rule 33. Motions in arrest of judgment are governed by Rule 34. Both Rules declare that the motions (other than a motion for a new trial based on newly discovered evidence) must be filed *within 5 days after verdict or within such further time as the court may fix during the 5-day period.* All of defendant's motions relating to a new trial and in arrest of judgment were made 28 days after the verdict and no extension of time was sought within the 5-day period following the verdict.

Under these circumstances, it is settled that the motions came too late and that the lower court was without jurisdiction to grant them even if it had wished to do so. *United States v. Smith,* 331 U. S. 469, 473-475 (1947); *Marion v. United States,* 171 F. 2d 185 (C. A. 9, 1949), cert. den. 337 U. S. 944.

VII.
Conclusion.

It is submitted that no error was committed by the lower court and that its judgment should be affirmed.

Respectfully submitted,

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Of Counsel.

APPENDIX A

United States Court of Appeals, Tenth Circuit. No. 4389—November Term, 1951.

United States of America, Appellant, vs. Tom G. Sanders, an individual, Appellee.

Appeal from the United States District Court for the Western District of Oklahoma.

[May 7, 1952.]

Robert E. Shelton, United States Attorney (James M. McInerney, Assistant Attorney General, John T. Grigsby and Vincent A. Kleinfeld, Attorneys, Department of Justice, and Paul S. Steffy, Attorney, Federal Security Agency, were with him on the brief) for Appellant.

Charles E. Dierker for Appellee.

Before Bratton, Huxman and Pickett, United States Circuit Judges.

Huxman, Circuit Judge.

On October 17, 1951, an injunction was entered against appellee, Tom G. Sanders, in the United States District Court for the Western District of Oklahoma, enjoining him from directly or indirectly introducing or causing to be introduced, and delivering or causing to be delivered, for introduction into interstate commerce, in violation of 21 U. S. C. 331 (a), a drug which was misbranded within the meaning of 21 U. S. C. 352 (b) (1), 352 (b) (2), 352 (e) (2) and 352 (f) (1). Thereafter this action was filed in the nature of an application for an order to show

cause why he should not be prosecuted for criminal contempt for a violation of the injunction.

Appellee, defendant below, filed a response to the order to show cause and moved that appellant's application be quashed and that no citation to show cause be issued. A hearing was had on appellee's motion. Judgment was entered denying appellant's application for a citation to show cause. While the trial court made findings of fact and conclusions of law, they are based entirely upon the allegations of the application for the show cause order and the statements of the parties at the time of the hearing thereof and not upon evidence introduced bearing upon the issue of appellee's guilt. That issue could not be before the court for determination until a show cause order had issued. Neither did the decree of the court attempt to pass upon the guilt or innocence of appellee. It merely denied the application for a show cause order on the ground that the allegations of the application were insufficient to state an offense.

Appellee's challenge to the jurisdiction of this court on the ground that the judgment of the trial court constituted an adjudication of guilt and is, therefore, not appealable is not well taken. It is clear that the trial court did not try the issue of guilt or innocence of the appellee. It merely passed upon the sufficiency of the allegations of the application to state an offense, if found true.

An application to show cause why defendant should not be prosecuted for criminal contempt is equivalent to an information charging criminal contempt, under Rule

42 (b) of the Federal Rules of Criminal Procedure, and a criminal contempt proceeding is a criminal case within the meaning of 18 U. S. C. 3731. An order dismissing a criminal contempt proceeding is appealable under the Criminal Appeals Act.[1]

It is admitted that the drug in question was misbranded. Appellee's position adopted by the court is that his activities do not constitute interstate commerce as prohibited by the injunction. Prior to the injunction, appellee engaged "runners" or "drummers" who went into states other than Oklahoma and solicited orders for the drug. After the injunction, this method of doing business was discontinued. Appellee sold only to those who came to his place of business at Wanette, Oklahoma, and delivered the drugs to them there. Many of these customers came from states other than Oklahoma.

The application for the order to show cause among others alleged that since the issuance of the injunction appellee had at various times and with full knowledge and notice delivered or caused to be delivered for introduction into interstate commerce various quantities of the misbranded drug; that on January 24, 1951, he sold and delivered to Loyd Mangan of Garden City, Kansas, for introduction into interstate commerce two one quart jars of said misbranded drug, with the knowledge that Mangan intended to and would return to Garden City, Kansas,

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[1]United States v. Goldman, 277 U. S. 229;
United States v. Hoffman, 161 F. 2d 881.

with said article or drug. The complaint alleged five other specific sales made to out of state customers and alleged that all of said sales were made with the knowledge that the purchaser was from out of the state and intended to and would return to his place of residence out of the state with said drugs. It alleged that while appellee ostensibly discontinued the practice of using salesmen or so called "runners" to solicit and fill orders from customers outside of the state of Oklahoma he had adopted the practice of selling and delivering his products at Wanette, Oklahoma, directly to out of state customers, soliciting them to return at later dates for more of the product, knowing that at all times said misbranded drug would be transported in interstate commerce by said purchasers for use in other states; that by such conduct he was disregarding and circumventing the decree and was in truth and in fact continuing to engage in the interstate business in the misbranded drug and was indirectly introducing or causing it to be introduced into interstate commerce, in violation of the injunction. For the purpose of considering the correctness of the trial court's ruling on the motion for dismissal of the application, these allegations stand admitted and must be accepted as the facts.

As stated by the Supreme Court in United States v. Walsh, 331 U. S. 432, 34, "The Federal Food, Drug, and Cosmetic Act rests upon the constitutional power resident in Congress to regulate interstate commerce. To the end that the public health and safety might be advanced, it seeks to keep interstate channels free from deleterious,

adulterated and misbranded articles of the specified types. * * * It is in that interstate setting that the various sections of the Act must be viewed." The Act must be given a reasonable construction to effectuate its salutary purposes. It prohibits not only the introduction into interstate commerce of adulterated articles but also the delivery thereof for introduction into commerce. One is as much a violation of the Act as the other. There is a long line of cases beginning with Dahnke-Walker Co. v. Bondurant, 257 U. S. 282, holding that where one purchases goods in one state for transportation to another the interstate commerce transaction includes the purchase as well as the transportation.[2] The court sought to distinguish the Dahnke-Walker case on the ground that the wheat purchased by a resident of Tennessee in Kentucky for transportation to Tennessee was delivered by the vendor to the vendee on board the cars of a common carrier, to be immediately forwarded to the purchaser's mills in Tennessee. The decisions, however, make it clear that whether delivery for transportation is made to a common carrier, a private carrier, or even to the purchaser for transportation by himself is immaterial.[3]

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[2]Addyston Pipe & Steel Co. v. United States, 175 U. S. 211;
United States v. Rock Royal Co-op., 307 U. S. 533;
United States v. Simpson, 252 U. S. 465;
Carter v. Carter Coal Co., 298 U. S. 238;
United States v. 7 Barrels, etc., 141 F. 2d 767.

[3]United States v. Simpson, 252 U. S. 465;
Tobin v. Grant, 79 F. Supp. 975.

To be guilty of violating the Act, it was not necessary that appellee be engaged in interstate commerce with respect to a misbranded drug. It was sufficient if he was engaged in delivering such a drug for introduction into interstate commerce. If appellee knowingly and regularly sold misbranded drugs and delivered them, knowing that they were purchased for transportation in interstate commerce, and solicited customers to return for future purchases and deliveries, he was guilty of a violation of the Act. The allegations of the complaint for a show cause order alleged that he did all of this and for the purpose of the motion they stand admitted as true. We accordingly conclude that stated an offense and that the trial court erred in dismissing the application for a show cause order.

The judgment is REVERSED and the cause is REMANDED with directions to proceed in conformity with the views expressed herein.

A true copy.

Attest:

Clerk U. S. Court of Appeals, Tenth Circuit.